



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,886	07/26/2001	Elisabetta Bianchi	IT0013P	6305

7590 07/28/2005

Merck & Company Inc
126 East Lincoln Avenue
Rahway, NJ 07065

EXAMINER

BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,886

Applicant(s)

BIANCHI ET AL.

Examiner

Timothy M. Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

10

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received July 26, 2001.

Claims 1-22 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claims 1-14 and 17-21, drawn to a compound of Formula I comprising Pep-A'-B'-C'-D', classified in class 424 subclass 189.1.
- II. Group II, claim 15, drawn to the use of a compound of Formula I in the manufacture of a medicament, classified in class 435, subclass 5.
- III. Group III, claims 16 and 22, drawn to a method of inhibiting HCV NS3 protease comprising administering a compound of Formula I, classified in class 435, subclass 235.1.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Groups I-III lack a corresponding technical feature because the compound of Group I lacks novelty in the art. Group I comprises a compound having Formula I wherein Formula I comprises the sequence Pep-A'-B'-C'-D'. Group I provides the following: A' may comprise any amino acid; B' may comprise valine; C' may comprise asperagine; and D' may comprise alanine. "Pep" is a peptide capable of binding NS3. Wang et al. anticipate the

Art Unit: 1648

compound of Group I in that Wang et al. disclose a NS3 epitope comprising the sequence Gly-Val-Asn-Ala (see e.g. col. 3, line 42). Groups I-III therefore fail share a special technical feature that makes a contribution over the prior art.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Invention I can be made using a variety of processes including solid phase synthesis and recombinant protein synthesis. Inventions I and II are therefore distinct for meeting the second requirement of MPEP § 806.05(f).

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process (MPEP § 806.05(h)). Here, the product of Invention I can be used in a diagnostic assay to detect anti-NS3 antibody. This process is materially different than Invention II's method of inhibiting HCV NS3 activity. Inventions I and III are therefore distinct.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this case, the specification lacks any teaching of how a method of manufacturing a product (i.e. Invention II) can be used with a process for using a product to inhibit NS3 activity (i.e. Invention III). Thus, Inventions II

Art Unit: 1648

and III are not disclosed as capable of use together. Inventions II and III also have different functions. Invention II synthesizes a compound, while Invention III inhibits the activity of NS3. Based on the foregoing, Inventions II and III are unrelated.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

As presented, the claims are drawn to five groups that each contain a set of patentably distinct species. For example, Group (i) consists of eight patentably distinct species of B' amino acid.

The species are as follows:

- i. The polypeptide of claim 1, wherein B' is selected from the amino acids listed in claim 5.
- ii. The polypeptide of claim 1, wherein C' is selected from the amino acids listed in claim 7.
- iii. The polypeptide of claim 1, wherein the combination of B'C' is selected from the amino acid pairs listed in claim 9.
- iv. The polypeptide of claim 1, wherein E' is selected from the amino acids listed in claim 11.
- v. The polypeptide of claim 1, wherein A', B', C', D', E' and F' are each selected from the amino acids listed in claim 12.

The species of Groups i-v are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

Art Unit: 1648

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of being used together because the specification fails to teach a combination therapy or compound diagnostic wherein more than one of the claimed species is used. The species of Groups i-v also have different effects. This results because the claimed species are drawn unique compounds that have different physical conformations and different immunological activities. Based on the foregoing, the species of Groups i-iv are unrelated.

Applicant is required, in reply to this action, to elect a single species for each of Groups i-v to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter**

Art Unit: 1648

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773.

The examiner can normally be reached on Monday - Friday, 8am - 5pm.


Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb


JAMES HOUSEL 7/25/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600